

**REMARKS**

Reconsideration of this application is respectfully requested.

**A. Status of the Claims**

Claims 29-32 and 50-64 are canceled herein, solely because those claims have been withdrawn from consideration as drawn to a non-elected invention. Applicant reserves the right to prosecute those or similar claims in a divisional application.

Claims 27, 28, 33-45, and 47-49 are amended herein. The amendments to the claims are fully supported by the application as filed and do not introduce new matter.

Claims 27, 28, and 33-49 are pending. Of those, claims 28, 34, and 37-41 are withdrawn as drawn to a non-elected invention. Applicant respectfully requests that those claims be rejoined to generic claim 27 upon a determination that generic claim 27 is allowable.

**B. Enablement Rejection**

Claims 27, 33, 35-36, and 42-29 stand rejected under 35 U.S.C. § 112, as allegedly lacking enablement. Action at pages 2-5. The basis for this rejection is the Examiner's assertion that, while the claims are enabled with respect to methods of treatment, they are not enabled with respect to methods of prevention. In response, Applicant notes that the claims have been amended to recite "treatment" but not "prevention". Accordingly, the basis for this rejection is moot and the rejection should be withdrawn.

**C. Anticipation Rejection**

Claims 27, 33, 35-36, and 42-29 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Joshi et al., U.S. Patent No. 6,277,882 ("Joshi"). Action at page 6. In support of this rejection the Office states that "Joshi et al. disclose the use of fumaric acid monoalkyl esters for preparing a pharmaceutical composition in the form of micro-tablets for treating psoriasis." Action at page 6. The Office also states that because "[t]he claims read on prevention and therefore the subject is not required to have the disease as claimed." Thus, the Office's reasoning is apparently that, because

the claims read on prevention and Joshi discloses administration to a human with a different disease (namely, psoriasis), that administration would constitute prevention within the scope of the claims.

Without addressing the merits of that position, and without conceding the correctness of that construction of the pending claims, Applicant notes that the claims have been amended to delete “prevention” and thus the claims now recite “the treatment of at least one of cardiac insufficiency, myocardial infarct and angina pectoris.” Joshi does not disclose administration to any subject to treat any of those conditions and so Joshi does not anticipate the claims. Therefore, the rejection for alleged anticipation should be withdrawn.

#### **D. Obviousness Rejection**

Claims 27, 33, 35, 36, and 42-49 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Joshi in view of McDonald et al., *British Journal of Dermatology*, Vol. 99, pp. 469-75 (1978) (“McDonald”). Action at page 8. In support of this rejection, the Examiner first observes that Joshi discloses use of fumaric acid monoalkyl esters for preparing a pharmaceutical composition in the form of micro-tablets for treating psoriasis. The Examiner acknowledges that Joshi does not disclose treatment of myocardial infarction. However, the Examiner contends that McDonald remedies that deficiency by “disclos[ing] that psoriasis is associated with an increased incidence of occlusive vascular disease to include myocardial infarction and that psoriasis predisposes to occlusive vascular disease.” Action at page 8. Applicant respectfully traverses.

The Examiner’s reasoning appears to be that McDonald’s disclosure that psoriasis is associated with an increased incidence of occlusive vascular disease to include myocardial infarction and that psoriasis predisposes to occlusive vascular disease, suggests applying a treatment of psoriasis to those conditions. At the outset, Applicant notes that McDonald does not in any way link the underlying disease mechanism of psoriasis with the underlying disease mechanism of myocardial infarction. That is not surprising, because in 1978 the underlying molecular disease mechanisms of these conditions were by and large unknown. Critically, absent such an

understanding, there was no reason for the skilled artisan to look to a psoriasis treatment to treat myocardial infarction.

Recently the U.S. Supreme Court addressed the issue of obviousness. *KSR Int'l Co. v. TeleFlex Inc.*, 127 S.Ct. 1727 (2007). The Supreme Court indicated that in certain circumstances, a modification or combination of the prior art that is "obvious to try" is indeed obvious. However, in order to create a *prima facie* case of unpatentability by rendering a claim obvious to try, the Supreme Court emphasized that it is necessary to find that a design need or market pressure to solve a problem, coupled with a finite number of identified, **predictable solutions**, would have given a person of ordinary skill a good reason to pursue the known options, and that in doing so the skilled artisan would **anticipate success**. *Id.* at 1733. Thus, under *KSR*, predictable solutions that anticipate success must be present to establish a *prima facie* case of obviousness under an 'obvious to try' rationale.

Applicant respectfully submits that, absent any suggestion in the art of a mechanistic or etiological connection between psoriasis and myocardial infarction, the skilled artisan would not have looked to a psoriasis treatment as a predictable solution for myocardial infarction. And certainly the skilled artisan would not have anticipated success in trying a psoriasis treatment as a myocardial infarction treatment. For those reasons the combination of Joshi with McDonald does not create a *prima facie* case that the claims are obvious and this rejection should be withdrawn.

#### **E. Conclusion**

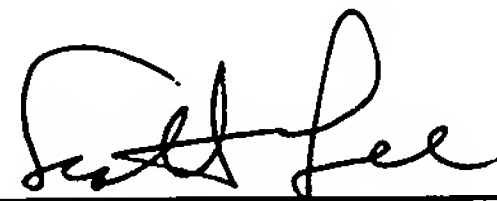
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: December 1, 2008

By:   
\_\_\_\_\_  
Scott M. K. Lee  
Reg. No. 59,574  
Tel. 202-408-6073